Exhibit E

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

JO HUSKEY AND ALLEN HUSKEY,	:	
Plaintiffs,	:	CASE NUMBER
v.	:	2:12-cv-05201
ETHICON, INC., ET AL.,	:	
Defendants.	:	

TRANSCRIPT OF TRIAL - DAY TWO

AUGUST 25, 2014

BEFORE THE HONORABLE **JOSEPH R. GOODWIN,**

UNITED STATES DISTRICT JUDGE

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Proceedings recorded by machine stenography; transcript produced by computer.

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MR. THOMAS: Your Honor, these are just kind of SEM images in the air. They're not tied to anything. They're scanning electronic microscopy images that aren't tied to anything, and I don't think there's an adequate foundation for them to be --

THE COURT: This time I have to sustain the objection.

MR. WALLACE: That's fine. Thank you, Your Honor.

BY MR. WALLACE:

Q. You mentioned a dog study. Can you tell me whether or not you reviewed any Ethicon documents relating to a dog study and whether -- I will just leave it there.

A. Yes, I did.

Q. Okay. And did you review those documents in connection with reaching your opinions in this case?

A. Yes, I did.

MR. WALLACE: 13152 would be the exhibit I'd like to offer, Your Honor, absent an objection.

THE COURT: Is there an objection?

MR. THOMAS: No, Your Honor.

THE COURT: It may be received.

MR. WALLACE: Thank you, Your Honor.

(PLAINTIFFS' EXHIBIT P-13152 WAS RECEIVED IN EVIDENCE.)

THE COURT: Make sure there's a paper copy provided to the Courtroom Deputy.

MR. WALLACE: Can we pull up --

THE COURT: And provide it to the Courtroom Deputy.

BY MR. WALLACE:

Q. Can you please -- do you have it in front of you, Dr. Guelcher?

A. Yes.

Q. Can you tell the jury what the document you have in front of you is and the document that they have on the screen in front of them?

A. So this is titled "Seven-Year Data for a Ten-Year Prolene Study."

Q. And what is the date of that?

A. October 15th, 1992.

Q. And, in reviewing this document in connection with the work that did you in this case, what conclusions did you draw?

A. Well, this document, again, showed evidence that the polypropylene was changing and cracking on the surface of the suture, that the Prolene suture was changing with time and cracking.

Q. In the interest of time, Dr. Guelcher, I want you to look at the conclusions that are found on the second page in the middle of the document.

A. Yes.

Q. And I'm just going to take those, again, one at a time.

Can you -- and you have reviewed the entirety of this

document?
A. Yes. It's very long. Yes.
Q. Can you tell me what impact that first bullet point that's the conclusion there had on your opinions in this case?
A. The seven-year in vivo results generally substantiated the five-year findings. They closely correspond to the observations of the explanted sutures of the dog that died prematurely, and these findings were that the Prolene was cracking with time and that was increasing with time.
Q. I'd like just -- just to take a step back and give the jury a little bit of context for this study. What do you understand the study, this study to be about and how long it went?
A. So, from my reading of the document, this study was designed to be a ten-year study in dogs, to understand the stability of the Prolene suture. So what happens -- how does the Prolene suture change over time, and it's implanted in a dog because this is -- we can do this in animals. You can't do these type of experiments in humans, and the dog is a good model, it's a large animal model. And so we can use these data to tell us something about how Prolene sutures would respond and how stable they are, how they'll react in a human.
And, again, it was designed to be a ten-year study. One of the dogs died prematurely, not related to the suture, at six years and ten-and-a-half months, and so they sacrificed

all the dogs at seven years so they could get the data. That's my understanding.

Q. And let's move on to the second bullet point. Tell me what, if anything, this second conclusion -- what impact, if any, it had on your opinions.

A. So the second conclusion states that degradation in Prolene is still increasing, and PVDF, which is another material that is less susceptible, so it's less reactive with oxygen, PVDF was more stable, in terms of cracking. So my -- what I learned from this was that, with the increased time, the degradation of Prolene is continuing. This is consistent with the idea that the foreign-body reaction doesn't stop. It just keeps going until the material is removed.

Q. Can you move on to the third conclusion and tell the jury, what, if any, impact that had on your opinions in this case?

A. Well, this is, again, noting that this reaction starts at the surface, so the eight explanted Ethilon sutures all showed heavy cracking, in many cases abrasion of the dyed surface layer. A decrease in the suture diameter was apparent in several cases. So Ethilon is a different type of material. It was also degrading. And they noticed a decrease in the diameter of the suture which, again, is consistent with this idea that it starts at the surface and works its way in, until you're gradually losing material until it works its way to the

middle of the suture.

Q. Just a point of clarification, Dr. Guelcher. Are -- PVDF, that's not Prolene, is it?

A. No, that's a different material. That's polyvinylidene fluoride. That's chemically different from polypropylene.

Q. Thank you.

Let's just move right on to the fourth bullet point. And tell the jury what impact, if any, that had on your opinions in this case.

A. Well, in this other type of material, they did not find any cracks. There were some scratches. What this tells me, that these four materials that they implanted were all degrading at different rates. Some of them were more affected by the reactive oxygen than others.

Q. Is Novafil polypropylene?

A. No.

Q. How -- how have the human Prolene suture study and this dog study, how have they impacted your opinions on mesh, if at all?

A. So, both the human explants that were explanted from humans out to eight years and the seven-year dog study both show that the polypropylene, the Prolene polypropylene, reacts with the oxygen that's secreted by these inflammatory cells and it changes the structure over time. So, as we progress from one to five, seven, eight years, these changes get more

severe, we see more cracking, more oxidation, more changes in the properties of the polypropylene.

This is basically happening because of this foreign-body reaction. And, in my opinion, these changes, because the mesh is also made from propylene, this reaction with oxygen, these changes in the surface will also occur with the mesh because it's made from the same base material, propylene.

Q. So, I'll try to ask it this way, Dr. Guelcher. Does the fact that this is a Prolene suture affect at all your opinion on what you referred to as the more-mesh opinion?

A. So, I think it's very important to remember that a suture implanted under the skin or in a blood vessel is very different than mesh implanted in the pelvic floor. Mesh has a lot more polypropylene, a lot more Prolene, a lot more surface, that can react with this oxygen.

So, I think what we can learn from the suture study is that the Prolene is unstable and it reacts in the body. Whether -- in this -- in my view, would lead to more studies with the mesh actually in the anatomic location where I want to use it, in the pelvic floor.

How does this oxidation affect the mesh in the pelvic floor? This is, to me, an important unanswered question. But what these studies point to is that Prolene does change over time. That's my conclusion.

Q. Well, since we're talking about Ethicon documents, beyond the documents that the jury has seen and that have been offered into evidence, did you review any other Ethicon documents?

A. I reviewed a number of other Ethicon documents. These are the two that struck me as the most -- in forming my opinions.

Q. And in reviewing those Ethicon documents, did you see any other studies like these that were actually done on the TVT-O mesh or mesh of any kind?

A. There are a number of other studies looking at mesh, complications of mesh, and what happens to mesh when it's implanted in the body.

Q. Well, my question is more specific than that, Dr. Guelcher.

My question is, specifically, in all of the internal company documents that you reviewed, did you see whether or not Ethicon ever did any sort of explant studies on their mesh?

A. I haven't seen those documents, no.

Q. Is that at all important to you as a biomedical engineer and how it might impact your opinions in this case?

MR. THOMAS: Objection, Your Honor.

THE COURT: Sustained.

BY MR. WALLACE:

Q. Now, when you looked at these Ethicon documents, who provided those to you?

MR. THOMAS: I'm going to object to the generic description of documents. I really don't know what he's talking about. I don't think the witness does either.

THE COURT: Sustained. The documents that have been admitted into evidence, you may inquire about certainly.

MR. WALLACE: Thank you.

THE COURT: I'm not trying to limit you. I'm just trying to hurry it.

MR. WALLACE: Okay. Sure. Then why don't I move on.

BY MR. WALLACE:

Q. Did you -- in connection with the work that you've done on polypropylene, have you reviewed any literature?

A. Yes. There is a number of published papers on these meshes and how they respond.

Q. In connection -- are you familiar with Drs. Costello and Clavé?

A. Yes.

Q. Have you reviewed their work?

A. Yes, I have.

Q. Can you tell the jury -- can we go to the --

MR. THOMAS: Before you publish anything, may I have a copy of whatever you're going to publish?

MR. WALLACE: It's in the PowerPoint.

MR. THOMAS: Well, it's quotes from the study. I object to this, isolated quotes from the study, Your Honor, as opposed to the full study.

THE COURT: Do you have a copy of the full study that you can provide counsel? If that's what you plan to introduce.

MR. WALLACE: It's just the articles. They're marked as exhibits. I'll give you the exhibit numbers, David. I believe you have a copy in front of you.

THE COURT: Why don't you two get together.

MR. WALLACE: Sure.

THE COURT: Maybe over that way a little bit.

(Discussion held off the record between Mr. Wallace and Mr. Thomas.)

MR. WALLACE: Your Honor, may I proceed?

THE COURT: You may.

MR. WALLACE: And, Mr. Thomas, you have the article.

BY MR. WALLACE:

Q. In connection with your work, did you perform a literature search?

A. Yes, I did. I searched a number of papers on this.

Q. And in connection with your work, did you come across any articles that dealt with polypropylene degradation in explants?

A. Yes, I did.

Q. And what articles were those?
A. Well, I've selected three that I believe make the point, by Clavé, et al., and published in 2009; by Costello, et al., published in 2007; and by Wood, et al., published in 2013.
Q. And, for the record, the Clavé article is Exhibit 21457.
A. Yes, that's right.
MR. WALLACE: And absent an objection, I'd like to be able to publish it to the jury.
THE COURT: 21 -- the number is?
MR. WALLACE: 21457.
THE COURT: 21457 may be admitted when presented to the Courtroom Deputy.
(PLAINTIFFS' EXHIBIT P-21457 WAS RECEIVED IN EVIDENCE.)
MR. WALLACE: Thank you.
Your Honor, as a learned treatise, we'd -- it's my understanding we would not be ultimately providing that to the jury.
THE COURT: All right.
THE DEPUTY CLERK: It does not go to the jury?
THE COURT: That's correct.
MR. WALLACE: Correct. But we would like to publish.
MR. THOMAS: Yes.
MR. WALLACE: Thank you.
BY MR. WALLACE:
Q. So let's keep moving on, Dr. Guelcher. The article is in

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TRANSCRIPT OF TRIAL - DAY SEVEN

SEPTEMBER 02, 2014

BEFORE THE HONORABLE **JOSEPH R. GOODWIN,**

UNITED STATES DISTRICT JUDGE

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THE COURT: Ladies and gentlemen, I think that we've done very well. We haven't had to take very many unscheduled breaks. This is a time when we have to take one.

Ten-minute break -- make it 15, and we'll look and see how the morning goes. Do a 15-minute break.

I hope you enjoy that healthy stuff that's back in the jury room. And I'll call you back when we're ready.

Court stands in recess.

(The jury left the courtroom at 10:03 a.m.)

(A recess was taken at 10:03 a.m.)

(The jury entered the courtroom at 10:22 a.m.)

THE COURT: Okay. Mr. Thomas.

MR. THOMAS: May I proceed, Your Honor?

THE COURT: Yes, sir.

BY MR. THOMAS:

Q. Dr. Thames, before the break I was asking you about defendants' exhibit 23228 which is titled *Seven Year Dog Study*. Did you review this document in connection with your work in this case?

A. Yes, I did.

Q. And you relied on it for some of the opinions you have in this case?

A. Yes, I did.

MR. THOMAS: Your Honor, I'd offer into evidence defendants' exhibit 23228.

MR. KUNTZ: No objection.

THE COURT: It may be received.

(Defendants' Exhibit 23228 received in evidence.)

BY MR. THOMAS:

Q. Dr. Thames, what is the *Seven Year Dog Study*?

A. A study where a number of dogs were used to implant Prolene into the dogs and they were maintained over a period of a number of years, in this case seven years, and at intervals some of the dogs would be sacrificed. The sutures, the Prolene sutures that were implanted in the dog would be removed and would be evaluated, evaluated for molecular weight, evaluated for tensile strength, evaluated for elongation, and other features like the infrared spectroscopy would be done and so forth. And at the end of seven years the last dogs were used. And this study compiles data that was collected in that manner for over a seven year period.

Q. Dr. Thames, the jury has already heard a little bit about this study in the examination of Dr. Guelcher last week. I want to direct your attention to page 115, excuse me, 116 of this document. Jamie, could you pull that up, please?

Do you have that in front of you, Dr. Thames?

A. Yes, sir.

Q. Right in the middle of the page there's a heading called optical microscopy and scanning electron microscopy. Are those analytical chemical techniques?

A. Yes, sir.
Q. Can you tell the jury what optical microscopy and scanning electron microscopy is?
A. Sure. Optical microscopy is looking through a microscope with no unnecessary additional energy input into it, with good lighting assistance and so forth, typical microscope, but a sophisticated one and fairly expensive.

Scanning electron microscopy is a technique in which a sample is placed in an instrument, it's bombarded with an electron beam, and that electron beam then is reflected on to a mirror of sorts and that produces an image, and that image is of a surface that it's looking at. It can be very high magnification, five, six, seven thousand times, and it's a good way of looking at fine structure of a material.
Q. Under the heading conclusions, the second bullet point reads, "Degradation in Prolene is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking."

What does that report mean from a scanning electron microscopy perspective?
A. Well, it suggests and states that the surface of the Prolene explant that they saw cracks and that it would -- they think it will continue to crack.
Q. And as a polymer chemist, if there is degradation in terms of cracking in the polypropylene, what would you expect

to find?
A. You would expect -- you would not only expect to find, you would find a loss of, and they allege that this is degradation, a loss of molecular weight, and you would change different properties, tensile strength and elongation would be changed from the normal not exposed sample.
Q. Now, let's go back to the page 115 right before and under IR and IR microspectroscopy. Could you tell the jury what that is, please?
A. IR microscopy is infrared microscopy where an electron beam hits the sample, reflects back to a sensor and it shows the picture of the surface that you're looking at. Microspectroscopy is looking at a very, very fine small point under a microscope. In other words, if you find an area under a microscope, you can zero in on a very, very small area and run an infrared spectra or see the spectra of that particular compound, whatever that might be at that pinpoint type area.
Q. And this report is October 15, 1992, is that right?
A. Yes, sir, that's correct.
Q. And that's seven years into the test?
A. Yes, sir.
Q. Under the second paragraph, under the IR and IR microspectroscopy, it reads, "IR microspectroscopy was used to examine cracked areas in Ethilon, Novafil and Prolene." Just for the jury's benefit, what are Ethilon and Novafil?

A. They're not Prolene, they are different structures of materials, sir.

Q. It says, "IR spectra obtained for cracked Prolene specimens, paren, figure A, showed possible evidence of slight oxidation, paren, a broadened weakened absorbance at about 1650 C M minus one."

What does that mean to you as a polymer chemist?

A. Well, when I see the term *shows possible evidence*, that means it's not clear and not concise, that it's possible. Most anything is possible. Then they say a broadened weak absorption at about 1650 reciprocal centimeters. My mind would jump to the fact that the 1650 reciprocal centimeters is an absorption frequency in the infrared that would be an area where you would expect to see proteins perhaps, and that more likely than you would see proteins then, of course, you would see any degradation from polypropylene or Prolene. So my feeling is that we are looking at something that's not Prolene, it may even be an acid salt, but not Prolene.

Q. How would proteins get on to this suture?

A. Proteins are in flesh. When they take the explants out, and they didn't clean these in any way, they didn't put them in any sort of chemicals for anything, they're on flesh, you would expect to see proteins from the flesh.

Q. Down the next paragraph there's a heading for IV and GPC. What is GPC?

A. Gel permeation chromatography.
Q. Tell the jury what GPC does.
A. GPC is a standard method for determining molecular weight. If I wanted to know the molecular weight of a polymer, I would use the instrument called the gel permeation chomatograph. What you do in a situation like that is you dissolve the polymer in a solvent, typically halogenated hydrocarbon. You inject it into a machine that has columns in it that separate chemical species by virtue of their size and molecular weight. And as they elude from that column, the gel permeation chromatograph measures the numbers of materials, the weight, puts it into the computer, and at the end of the run it provides you information about the molecular weight of the sample that was just analyzed.
Q. And read this with me for the jury, please. It says, "Gel permeation chromatography, paren, GPC, was run on Prolene sutures explanted from dogs after seven years." What does that mean?
A. They took the sutures, Prolene sutures from the dogs after seven years.
Q. And it says, "The GPC data was compared to data from a current 4 slash O Prolene suture." What does that mean?
A. That means that they took the experimental sample from the dog and they ran its molecular weight, and then they compared it to a pristine sample of Prolene that had never

been introduced to anybody, right out of the box so to speak, brand new.

Q. And why do you do that kind of analysis?

A. Called a control. In other words, if we want to know if the molecular weight of the Prolene was reduced while it was in the dog, then we need a standard or control, so we use the unused, unimplanted material as a control. This is what your molecular weight ought to be. And then you test the sample from the dog and say, well, is it the same or is it within experimental error. If it is, then nothing has happened to the molecular weight this seven years. The polymer has not degraded.

Q. So continue reading on with me. "The results indicate that there was no significant difference in molecular weight between the 4 slash O Prolene control and the seven year explants."

What does that mean to a polymer chemist?

A. That means that there was no degradation because of implantation of Prolene in the dog over a seven year period of time.

Q. Had there been degradation, what would you expect to see?

A. You would have seen a reduction in molecular weight would be one thing that you would expect to see.

Q. I want to direct your attention now to page 153 of this, of exhibit 23228. 153 is an interim report dated October 19,

1992. Do you see that?
A. Yes, I do.
Q. Tell the jury what this document is.
A. Well, this is a document that shows the physical properties of explanted materials, in particular we're interested in Prolene. It measured the physical testing, it took these samples and did tensile strength and elongation studies on them and we talked about that earlier today. And they have a chart in here which I think we'll get to a little bit later that will show you what happens to the physical properties of Prolene over the seven year period.
Q. And what were the findings -- strike that.
What different tests did they run, Dr. Thames?
A. They ran tensile strength test, which is the pull test, to determine how much force you have to put on the sample to break it. And then they determined elongation, which is how much did it extend before it finally broke. And finally they looked at modulus, which is a measure of stiffness to see if it was stiffer than when it was implanted or as stiff as when it was implanted just to get a handle on what the characteristics of stiffness was of that explanted material.
Q. Dr. Thames, what did Ethicon find after seven years of implantation happened to the tensile strength of these sutures?
A. They found that the tensile strength was reduced, as far

as my memory, it's about five PSI, slight reduction in the strength required to break the Prolene sample.

Q. What did the Ethicon scientists find with respect to elongation?

A. The sample elongated twice its original length. The first length was like 37, 38, something like that, I forget exactly the number, and finally upon explantation after seven years it was twice as elongatable.

Q. And what's the significance of the changed elongation?

A. Well, when you talk about just a very, very small reduction in strength and a very long elongation, the area under that curve of is far greater after seven years of explantation than before.

Q. Tell the jury and me what it means, area under the curve, as it relates to the ability of the suture to perform its intended function.

A. Remember we talked about the fact that the area under the curve was a measure of toughness. So what that means is that not only, not only did the Prolene explant not undergo degradation, but it improved with implantation. It became tougher. It became more elongatable with only a very minor reduction in tensile strength. So it was a tougher strand of polypropylene after seven years than it was when it was implanted in the dog.

Q. Finally, Dr. Thames, you talked about Young's modulus

test?
A. Yes, sir.
Q. Tell the jury about that, please.
A. Modulus is a test of toughness and typically slope of the curve, and since I didn't have the exact numbers I couldn't give you a curve that showed the exact shape of the modulus curve, but it's reduced somewhat, and that means the stiffness was reduced a bit during the period of time when it was being implanted. So we, we reduced stiffness, we improved elongation with very minor changes in tensile strength, and so overall the properties were enhanced during the seven year implantation.
Q. Dr. Thames, I put a slide up there that shows the data and the cover page, page 115, so the jury can see it.
A. Yes, sir.
Q. And the citation there says that "Novafil samples show a decrease in breaking strength while Prolene and PVDF showed no significant change after seven years of implantation." That refers to the breaking strength?
A. Yes, sir. Or tensile strength, the same thing. We're going to call it the same thing, okay.
Q. And is the other data up there, is that the data upon which you relied for your opinions about the Prolene becoming tougher after seven years?
A. Yes, sir.

Q. Can you explain to the jury how you read that data just so they understand?

A. If you look at the chart that says, the first segment says zero in the top line, that's at implantation. That's at the beginning. And then they measured the breaking strength or the tensile strength was 1.68, that's before it was ever implanted. And then after implantation, which is over here under the seven column, breaking strength is 1.60. So the actual strength to break it reduced by point 08 pounds or Newtons.

And then in terms of the elongation, which is the second group of numbers, the original elongation was 37 percent at zero time of implantation. After seven years it was 78 percent, 78 percent, which means that it's doubled its elasticity during the period of time that it was implanted.

And then the modulus was originally 721 and it went to 214 after seven years with a reduction of minus 70 in modulus, meaning it became more flexible, more pliable, less stiff.

Q. Can I have the next slide, please, Jamie?

Dr. Thames, I have a slide up called *Seven Year Dog Study Break Strength Versus Percent Elongation*. Can you explain that to the jury, please?

A. Yes, sir. I've taken the numbers that we just talked about in the table by the Ethicon scientists and I have plotted them in terms of breaking strength is on the vertical

column or tensile strength, elongation is on the horizontal column. The red represents the original Prolene before it was inserted into the dog, implanted; the blue represents the data that was collected from the explanted sutures after seven years of implantation in the dogs.

You'll notice the blue had a very small decline in breaking strength, as we said, point 08 pounds, but its elongation went out to 78 percent. So if I measure the area under the red and compare that area to the area under the blue, we can see that the area under the blue is twice or perhaps more than the area under the red. And when we understand that the definition of toughness is area under this stress strain curve, it's obvious then that the Prolene implant improved its toughness over the period of the seven years it was implanted in the dog.

Q. And from a polymer chemistry perspective, how can it improve?

A. It can improve by being able to be plasticized. For instance, we talked about the fact that polypropylene was a group of chains and you pull them, and as you pull them they began to stretch out and so forth, like the spaghetti that we talked about. Well, if you implant this in an animal or in human flesh, the body, there are lipids there, there are fats. Unfortunately there's probably too much on those that would be put in me because I'm a little overweight, but every human

body has a certain amount of fat in it, and those lipids are fats, they're triglycerides, we go to the doctor and have our triglycerides and our cholesterol looked at, and we know we have them in our body. Well, they can plasticize and make more pliable a molecule like Prolene.

Now, in order to understand that, I think I have to maybe use a human example. There have been times when, you know, I've worked in my shop and I've gotten grease on my hands and I've wiped it off with an organic solvent, and my hands felt dry and they felt rough. First thing I do is reach over for some hand lotion and rub it into my hands. I bet you there's been times when most of you all and I've also washed dishes at times. And when you get through washing dishes, your hands feel a little dry and a little rough, and the first thing you do is you reach over and put lanolin and lotion on them. What you're doing is putting a plasticizer on your hands so that the plasticizer can soften, move in between the molecules of your hand, your flesh, and provide elasticity and lubricity, and that's what happened here is the lubricity has been improved for the polypropylene or Prolene implant.

Q. How about a little glass of water?

A. I think I need it.

Thank you.

Q. Next slide, please, Jamie.

Jamie, next slide, please.